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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,434	01/07/2002	David Wallach	WALLACH=1D	4966

1444 7590 06/02/2003

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	4

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,434	WALLACH ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Currently, claims 1-10 are pending and under consideration.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 5,512,544. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below. The present claims 1 and 3-6 are not patentably distinct from claims 1 and 12 of the US patent: claims 1 and 12 of the US patent is directed to a method for the treatment of an

autoimmune disease or graft-versus-host in a patient using a protein having a sequence corresponding to that of the binding site of the cell surface TNF receptor type I and II (claim 1) or a protein having a sequence corresponding to that of natural or recombinant TBP-I or TBP-II (claim 12), and wherein both proteins have the same ability to bind to TNF as natural or recombinant TBP-I or TBP-II. Although the claims in the patent do not identify the protein with a SEQ ID NO (as in the present claims 1, 5 and 6) or the physiochemical features (as in the present claims 3 and 4), the protein is the same as that of the present invention in light of the disclosure of the patent, which defines the protein used in the method as that of US 07/243,092, including the amino acid sequence SEQ ID NO:1, having ability to interact with TNF to inhibit the binding and the cytotoxic effect of TNF (column 2, the last paragraph). SEQ ID NO:1 of the patent is identical to SEQ ID NO:1 of the present invention, and has the same physiochemical features as those in the present claims. Thus, the structural and functional limitations for the protein in the claims of the patent meet those of the present claims. Further, treatment of an autoimmune disease or graft-versus-host in the claims of the patent represents a species of "treating conditions" wherein TNF ... is to be eliminated ... or its effect in the body is to be antagonized" in the instant claims, and therefore, anticipates the instant claims to a genus of "treating conditions" (see MPEP 2131.02). As such, the present claims 1 and 3-6 are not patentably distinct from claims 1 and 12 of the patent.

With respect to claims 2 and 7-10, they are not patentably distinct from claims 1 and 12 of the US patent: although claims 1 and 12 of the patent do not recite the limitation of "for *reducing* the cytotoxic activity of TNF" as that in the present claims 2 and 7-10, such activity exist inherently in the claimed method of treatment in the patent because the proteins used in the methods of the patent and the instant claims 2 and 7-10 are the same for the reasons above, and the disclosure of the patent teaches that the protein used in the method has the ability to interact with TNF to inhibit the binding and the cytotoxic effect of TNF (column 2, the last paragraph, and Example 4). As such, the present claims 2 and 7-10 are not patentably distinct from claims 1 and 12 of the patent.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method for treating conditions or reducing the cytotoxic activity of TNF using a polypeptide encoded by a nucleic acid encoding SEQ ID NO:1, and the complete sequence and functional fragments thereof, does not reasonably provide enablement for claims to a method for treating conditions or reducing the cytotoxic activity of TNF using a polypeptide encoded by any nucleic acid whose complementary sequence hybridizes with a nucleic acid encoding SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 5 and 9 are directed to a method for treating conditions and reducing the cytotoxic activity of TNF using a polypeptide encoded by *any* nucleic acid whose complementary sequence *hybridizes* with a nucleic acid encoding SEQ ID NO:1. Such sequence limitation reads on any or all polypeptide molecules whose polynucleotides would hybridize to the polynucleotide encoding SEQ ID NO:1 under non-specified conditions. It is well known in the art that hybridization will occur even under stringent conditions if there is only local identity between two molecules whose sequences might be totally divergent outside of that region, and hybridization would be expected to occur under low stringent conditions if two molecules share only certain degree of sequence homology. Such hybridized molecules may encode proteins capable of interacting with TNF, yet having other distinct biological functions from those of the SEQ ID NO:1, and complete molecule or fragments thereof. The specification provides no guidance as to a specific hybridization condition for obtaining the claimed species useful in the

method, or working examples of any of such variants, which would be within the limitations of the claims. Therefore, it would require undue experimentation in order to make the claimed invention in its full scope.

Due to the large quantity of experimentation necessary to determine how to make the invention commensurate in scope with the claims, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that hybridization would occur between molecules share only local or low degree of sequence homology, and the breadth of the claims which embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make the claimed invention in its full scope.

Claims 5 and 9 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The specification discloses *one* polypeptide with physical/chemical, partial sequence, and functional particularities, and no other variants thereof meeting the limitations of the claim were ever identified or particularly described. The present claims 5 and 9 encompasse significant structural dissimilarity as compared to the specified polypeptide. A skilled artisan would not be able to reasonably expect, for example, the requirement that a molecule hybridizing to said nucleic acids would correlate with the translation of a protein and retention of biological properties characteristic of the protein described in the disclosure. The Office therefore concludes that a single species of the protein is not representative of all variants recited in the claim, and thus that the disclosure does not convey to those skilled in the art that the inventors

were in possession of the genera of variants with partial sequence similarity to the nucleic acid encoding the TNF binding protein, and with or without the defined biological activity at the time the application was filed.

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Creasey et al. (Proc. Natl. Acad. Sci. USA, 1987, 84(10): 3293-7, provide by applicants) discloses that a hTNF receptor, having a high molecular weight and noncovalently linked membrane-bound polypeptides, is associated with cytotoxicity (the abstract).

Hass et al. (J. Biol. Chem., 1985, 260 (22): 12214, provide by applicants) discloses that hTNF-β binds to mouse fibroblasts and cause the ultimate cell lysis, and that neutralizing antibodies to hTNF-β efficiently inhibited the binding of hTNF-β to the cells (the abstract).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
5/28/03